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A randomized trial evaluating the accuracy of AF detection by four external ambulatory ECG monitors compared to permanent pacemaker AF detection

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Abstract

Purpose Several external cardiac monitors (ECMs) have recently been developed. These have never been compared to 'gold standard' monitoring with concurrently implanted DDDRP pacemakers. The accuracy of AF detection of Zio XT Monitor (ZM), NUUBO Vest (NV) and Carnation Ambulatory Monitor (CAM) compared with Novacor 'R' Test 4 (RT) in patients (pts) with DDDRP PPM advanced Holters as the comparator, was evaluated.

Methods Twenty-one pts. with AF and a DDDRP PPM, each acting as their own control subject, wore every ECM for 2 weeks in randomized order. PPM downloads were performed at application and removal. Device ECGs were compared for AF burden and individual AF episodes with PPM Holters. Pt acceptability, wear time, costs and time expenditure were evaluated.

Results RT AF burden was less accurate than the ZM, NV or CAM ($p < 0.05$). Probability of inaccurate AF diagnosis was higher for RT than ZM or CAM OR 12.31 and 5.85, respectively ($p = 0.025$ and $p = 0.042$). ZM wear time was longer than the RT: 307 h vs. 224 h; $p = 0.02$. Acceptability was greater for CAM than RT (1.86 ± 2.63 compared with 0.57 ± 1.17 for CAM; $p = 0.024$). All ECMs were more expensive than RT ($p < 0.00001$).

Conclusions All new ECMs were more expensive than the RT system; however, the ZM, NV and CAM are all more accurate than current standard practice RT device in AF burden assessment. The RT is more likely to give inaccurate diagnoses than ZM or CAM. This may have clinical implications.

Keywords Atrial fibrillation detection · Permanent pacemaker · External cardiac monitoring

1 Background

Detection of atrial fibrillation (AF) provides an indication for anticoagulation preventing catastrophic thromboembolic events [1, 2]. Inaccurate detection of AF could put patients at risk from serious bleeding events if anticoagulation is inappropriately commenced [3].

The majority of patients with AF are asymptomatic [4, 5]. Hence, spot rhythm check devices frequently fail to detect arrhythmia. AF detection thus requires continuous ambulatory ECG monitoring preferably for at least 4–5 days [6].

Dual chamber permanent pacemakers (PPMs) and implantable cardioverter-defibrillation devices are considered the reference standard in arrhythmia detection with high sensitivity and specificity for atrial and ventricular waveforms via endocardial electrodes [7]. No study has used these devices to assess efficacy of new external cardiac monitors (ECMs) now in use to diagnose AF.

The Novacor 'R' test 4 (RT) (Swanley, Kent, UK) is the most commonly used ECM in the UK, Europe, Asia and Africa, and has become a first-line investigation tool for intermittent palpitations. This medium-term monitor has a higher diagnostic yield compared with conventional 24-h Holter monitoring due to its increased monitoring duration [8]. Other novel ECMs may provide improved diagnostic accuracy and cost-effectiveness in arrhythmia detection. We compared three new cardiac rhythm monitoring technologies: ZIO XT monitor (ZM) (iRhythm San Francisco, CA, USA), NUUBO vest (NV) (NUUBO Smart Solutions Technologies, SL, Madrid) and Carnation Ambulatory Monitor (CAM) (Bardy Diagnostics, Inc., Seattle, WA, USA) with the clinical

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standard RT. The objective of this trial was to compare each of the four ECMs in a prospective randomized study in patients implanted with DDDRP pacemakers with known AF.

2 Methods

This study was performed at Eastbourne Hospital, East Sussex Healthcare NHS Trust, and complies with the declaration of Helsinki. The national research ethics committee approved the study. Written informed consent was obtained from all participants. Participants wore all three novel ECMs and the clinical standard RT in randomized order. An independent clinician using computer-generated random numbers performed the randomization. Participants were monitored with each of the four ECM devices for a 14-day period. There was no ECG monitoring for at least 7 days between each 14-day ECM application.

Devices were applied and analysed according to the manufacturers' instructions. The study ECMs were analysed by the manufacturers or agents using the same service as commercially available with each device. PPM interrogation and download were performed immediately before and immediately after each ECM application and removal. The time stamp from the PPM was coordinated with the time stamp from each ECM, as precise rhythm correlation was dependent upon this. The AF burden obtained during each PPM interrogation represented the amount of time spent in AF since the previous interrogation. All individual AF episodes detected by the PPM were saved with time, date and duration of the episode recorded.

2.1 Study population

Patients with DDDRP PPMs and a history of AF were recruited. PPM diagnostics in these devices are near identical with comprehensive Holters that have been shown to be > 95% specific and sensitive for AF burden measurement using 0.5-mV atrial sensitivity programming [9, 10].

2.2 Patient time expenditure

The total period of time expended by each study participant was calculated for each device including all travel time to and from hospital, total hospital waiting time for both application and device return if applicable.

2.3 Device costs

Total device costs were calculated and recorded for each device. These included cost of the device itself as well as costs of necessary administrative and physiologist staff, costs of patient travel to and from hospital, and electrode costs for the RT.

2.4 Device acceptability

After each 14-day monitoring period, patients completed feedback questionnaires by either a research physician or research physiologist utilizing visual analogue scores (VASs). Patient discomfort applying and wearing the monitor was recorded for each patient for each device using two horizontal VASs. The VAS comprised a 100-mm horizontal line anchored at the left with the statement 'no discomfort' and at the right with the statement 'worst discomfort'. Participants were asked to look at the line and think about how much discomfort they experienced attaching the device and how much discomfort they experienced whilst wearing the device. There were small vertical lines along the main horizontal line at centimetre intervals, and participants had to mark where they felt they most accurately reported their satisfaction with the device.

2.5 Device characteristics

See Table 1. The Novacor 'R' Test 4 used widely in the UK and Europe is reusable and can potentially monitor for up to 32 days although battery longevity is 7–14 days; see Fig. 1a [11]. Continuous analysis of every heart beat enabling arrhythmia detection during asymptomatic events is standard. A patient activation button allows capture of the loop memory to correlate symptoms with concurrent ECG; see Fig. 1b. Patients are required to change chest electrodes daily.

The Zio XT Monitor is a single-lead electrocardiographic (ECG) continuously recording ambulatory adhesive patch monitor allowing monitoring up to 14 days.

The manufacturers state that the device can record and measure true AF duration, defined as the documented and validated length of an episode of AF. The device allows

Table 1 Features of each external cardiac monitor

	RT	ZM	NV	CAM
Duration of monitoring (days)	32	14	90	7
Battery longevity (h)	336	336	24	168
Weight (g)	42	19	3	18
Water resistant	No	Yes	Yes	Yes
Number of leads	2	1	3	1
Patient symptom activation capability	Yes	Yes	Yes	Yes
Patient diary provided	Yes	Yes	Yes	Yes
Single device use	No	Yes	Yes	Yes

Table showing key features of each study cardiac monitor

CAM Carnation Ambulatory Monitor, *NV* NUUBO Vest, *RT* Novacor 'R' Test IV, *ZM* Zio XT Monitor

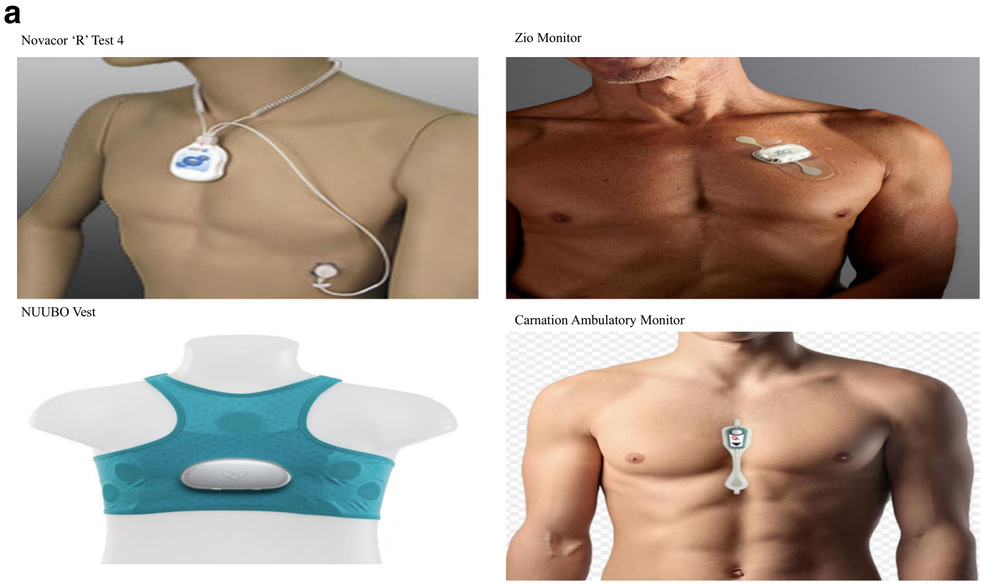
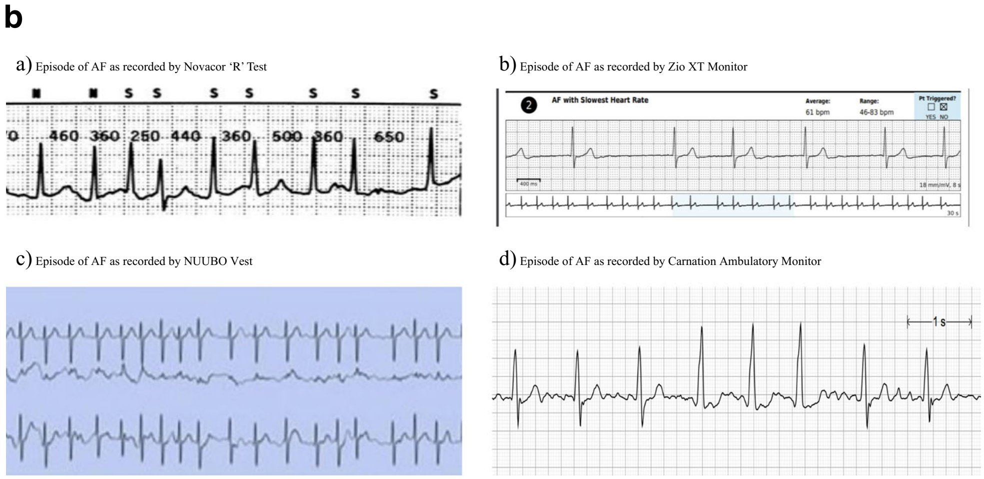


Figure of the clinical standard RT and the three study ECMs. The anatomical position while the ECM is in use is shown



a) Episode of AF as recorded by Novacor ‘R’ Test

b) Episode of AF as recorded by Zio XT Monitor

c) Episode of AF as recorded by NUUBO Vest

d) Episode of AF as recorded by Carnation Ambulatory Monitor

Figure providing examples of ECG traces for each of the study ECMs and the standard RT. In each case the tracing shows an episode of atrial fibrillation.

Fig. 1 **A** The ECMs used in each study phase. **B** Example of electrogram output for each external cardiac monitor. Figure providing examples of ECG traces for each of the study ECMs and the standard RT. In each case, the tracing shows an episode of atrial fibrillation. Abbreviations as in Table 1

patient-triggered symptomatic events to be recorded; see Fig. 1a, b. The ZM is returned to the company by the patient via free post.

The Nuubo Vest is a 5-electrode system consisting of an electronic device (nECG minder) attached to the garment transmitting the ECG signal via Bluetooth to a computer, a shirt that captures the ECG signal via textile electrodes (nECG vest) with data analysis via the nECG minder which must be charged for 30 min each day. Patient-triggered clinical events are recorded by pressing/tapping the device, see Fig. 1a, b. This device has the potential for long duration monitoring (up to 90 days) [12].

The Carnation Ambulatory Monitor is a P wave centric ECG patch according to the manufacturer and is placed on top of the atria over the sternum. The device allows patient-triggered clinical events to be recorded by button press correlating symptoms with ECG rhythm; see Fig. 1a, b. The device is designed for up to 7 days of use. Data can be retrieved directly at the application site or via post. All data are recorded and analysed for the entire wear time. Routinely, only the clinically longest and fastest AF events are recorded. ECG readers that contract with Bardy Diagnostics (BDx) are directed specifically to not conflate atrial flutter and atrial tachycardia with variable AV conduction, with AF.

3 Statistical analysis

Percentage AF burden was considered the primary variable providing the best overall assessment of AF status. Analysis was compared for maximal AF duration. The number of AF episodes and the detection or otherwise of clinically important AF were evaluated.

4 Primary analyses

Comparison of total AF burden between the ECM and PPM derived parameter during each phase was analyzed using a generalized linear model with identity link and Gaussian error to provide scatter fit plots with mean squared error and R squared assessment of fit.

5 Secondary analyses

Individual episodes of AF in each phase were analysed using a generalized model with log link and Poisson error comparison of ECM and PPM, modelling $\log_e$ count of episodes accounting for extra Poissonian variability through inclusion of a residual random effect. In addition, the likelihood of disagreement between the ECM and the PPM parameter was examined, comparing each with the performance of the RT in a logistic regression model. Patient satisfaction, patient wear time and total costs were compared between the groups using paired and unpaired Student's *t* tests. A *p* value of less than 0.05 was considered significant.

6 Results

6.1 Patient demographics

See Table 2. Thirty-three patients were screened. Twelve patients were excluded. Six patients were unable to commit to the duration of the study due to logistical difficulties, 4 patients refused consent and 2 patients had inadequate PPM atrial lead sensing.

Twenty-one patients were inducted. All had DDDRP PPMs in situ including eight Medtronic Ensura, three Medtronic Advisa, three Sorin Tilda, two Medtronic Adapta, two Medtronic Sensia, one Medtronic Sigma, one Biotronik Evia DR-T and one Boston Scientific Teligen 100. Eighteen participants had paroxysmal AF and three persistent AF.

The 21 participants had sensing and pacing DDDRP function reconfirmed throughout the study period with satisfactory atrial and ventricular sensing with EGMs available for all patients and phases. The mean study duration was 77 days. All 21 patients had an episode of AF at least once during the 14-day observation period.

Table 2 Demographics of study patients

	Mean (%)
Age (SD)	75 ± 7
Male	16 (76.2%)
Coronary risk profile	
Hypertension	17 (81.0%)
Diabetes mellitus type 2	3 (14.3%)
Hypercholesterolaemia	9 (42.9%)
Smoking history	10 (47.6%)
Family history of CAD	7 (33.3%)
Medication	
Direct oral anticoagulant	7 (33.3%)
Vitamin K antagonist	13 (61.9%)
Beta-blockers	9 (42.9%)
Statins	9 (42.9%)
ACE inhibitors	2 (9.5%)
ARBs	5 (23.8%)
CCBs	9 (42.9%)
TIA/CVA	0 (0%)
Chronic obstructive pulmonary disease	2 (9.5%)
Heart failure	4 (19.1%)
Ischaemic heart disease	8 (38.1%)
Anti-arrhythmic medication	4 (19.1%)
Sotalol	2 (9.5%)
Dronedarone	2 (9.5%)
Previous AF ablation	9 (42.9%)
Mean number of AF ablations per patient	0.71

Table depicting baseline demographics for the study participants. Data for key cardiac and non-cardiac co-morbidity is provided

6.2 AF burden detection

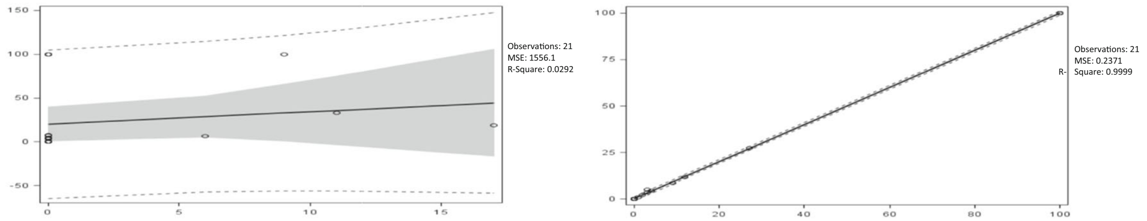
Fit plots for overall AF burden recorded by the four ECMs compared with concurrent DDDRP PPMs are shown in Fig. 2. The RT had R squared and mean squared error (MSE) for AF burden detection of 0.029 and 1556.1, respectively. The ZM had an R squared of 0.99 with an MSE of 0.24. The values for NV were 0.95 and 84.65 for R squared and MSE, respectively. Finally, CAM had an R squared of 0.96 with an MSE of 60.1. All the ECM devices were significantly better estimating AF burden than RT ($p < 0.0001$) using DDDRP Holters as comparator.

6.3 Arrhythmia episodes

A total of 1108 individual AF arrhythmia episodes were identified by DDDRP pacemakers during the study. PPM electrograms (EGMs) were analysed by two independent electrophysiologists to confirm the diagnosis of AF and/

a) ‘R’ Test AF burden vs. PPM AF burden

b) Zio XT Monitor AF burden vs. PPM AF burden



c) NUUBO Vest AF burden vs. PPM AF burden

d) CAM AF burden vs. PPM AF burden

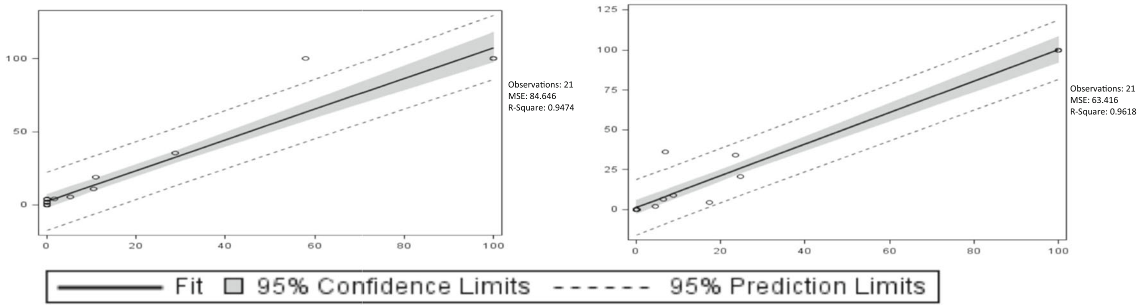


Fig. 2 Fit plots for AF burden recorded by the PPM vs. the AF burden recorded by the ECM. Figure showing AF burden as recorded by the PPM versus AF burden as recorded by the ECMs in each study phase. RT was found to have poor performance with very low R square and high MSE, and ZM has excellent performance with excellent R-square and very low MSE. CAM and NV show good performance with high R square and modest MSE. Abbreviations as in Table 1

or atrial arrhythmia and type. The time, date and duration of every AF episode were recorded and cross-correlated with the corresponding ECM report. The results are presented in Table 3. The RT significantly under reported episodes > 30 s (RR 0.508, 95% CI 0.281 to 0.918; $p = 0.027$) and performed with patient level uncertainty for episodes > 6 min (RR 0.773, 95% CI 0.502 to 1.191; $p = 0.2274$). Similarly, the ZM systematically under detected longer episodes (RR 0.809, 95% CI 0.757 to 0.864; $p = <0.0001$). The CAM had no systematic difference in the detection of episodes at > 30 s or > 6 min, and achieved these measures with high precision (narrow confidence intervals).

Table 3 Comparison of AF episodes by length category and 95% confidence interval

Category	Relative risk (95% confidence limits)	*p*
RT > 30 s	0.508 (0.281–0.918)	0.027
RT > 6 m	0.773 (0.502–1.191)	0.2274
ZM > 30 s	0.867 (0.804–0.935)	0.0008
ZM > 6 m	0.809 (0.757–0.864)	< .0001
NUUBO vest > 30 s	0.970 (0.945–0.995)	0.0224
NUUBO vest > 6 m	0.897 (0.757–1.062)	0.1923
CAM > 30 s	0.999 (0.980–1.109)	0.9372
CAM > 6 m	0.953 (0.931–0.977)	0.0007

Table depicting accuracy of detection (relative risk) of individual episodes of AF for each patient in each study phase compared to pacemaker. The lower the estimate, the closer the correlation to PPM detected AF episodes found. Abbreviations as in Table 1

6.4 Overall accuracy of AF detection

ZM and CAM more accurately indicated the presence or absence of AF than RT (odds ratio 12.3 (95% CI 1.4 to 110.3; $p = 0.025$) and 5.8 (95% CI 1.1 to 32.1; $p = 0.042$); Table 4). NV odds ratio was 2.0 (95% CI 0.5 to 7.5; $p = 0.3$) compared to RT, but this was not significant.

6.5 Patient satisfaction

CAM was associated with significantly less discomfort during initial application than the RT according to visual analogue scores: RT 1.86 ± 2.63 (95% CI 0.66 to 3.06) compared with 0.57 ± 1.17 (95% CI 0.04 to 1.10) for CAM; $p = 0.024$; see Fig. 3a. There were no significant differences between the other study ECMs and the RT. There were no significant differences in discomfort scores, whilst the devices were in situ throughout the study phase.

Table 4 Likelihood of correct diagnosis for test ECMs vs. ‘R’ test

Effect	Odds ratio	95% Wald confidence limits		*p* value
ZM vs. RT	12.3	1.4	110.3	0.02
CAM vs. RT	5.8	1.1	32.1	0.04
NV vs. RT	2.0	0.5	7.5	0.3

Table showing the statistical probability of having a correct AF diagnosis for each study ECM. The odds of correct AF diagnosis were 12.3 times higher for ZM than RT $p = 0.02$, 5.8 times higher for CAM than RT $p = 0.04$ and 2.0 times higher for NV than RT $p = \text{ns}$. Abbreviations as in Table 1

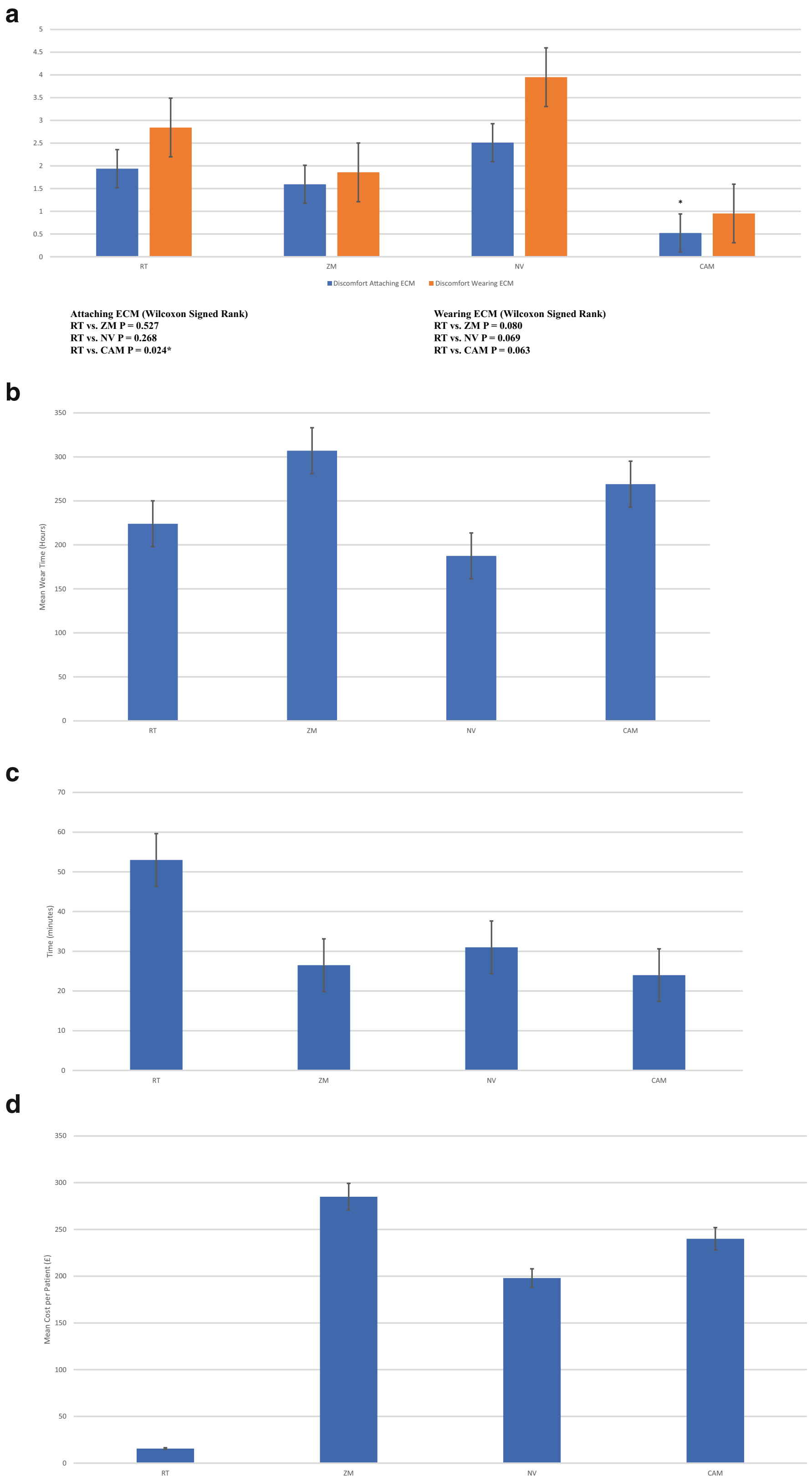


Fig. 3 **a** Mean discomfort associated with each ECM. **b** Mean wear time of each ECM. **c** Mean total patient travel time expenditure per device. **d** Mean cost per patient

6.6 Patient wear time

The ZM was worn for a longer mean duration than the RT; mean wear time of ZP 307 (95% CI 284.63 to 340.32) hours vs. mean wear time of RT 223.6 h (95% CI 178.43 to 268.31); $p = 0.016$, see Fig. 3b. There were no significant differences in wear time with NV or CAM compared to RT.

6.7 Patient time expenditure

The mean total patient time expenditure was longer with the RT than with any of the study ECMs (53 min for RT compared with 26.5 min (95% CI 20.1–36.0), 31 min (95% CI 20.6–36.6) and 24 min (95% CI 20.9–35.3) for ZM, NV and CAM, respectively ($p < 0.0001$; see Fig. 3c).

6.8 Total costs

The total cost of each ECM (including patient, administration, physiologist and clinician costs as well as device cost) is shown in Fig. 3d. The diagnostic level used was the most advanced available for each assessed device and therefore most expensive in all cases. All study ECMs were significantly more expensive than the reusable RT ($p < 0.0001$).

7 Discussion

Ambulatory monitoring is employed as a diagnostic tool for AF detection. However, there are no guidelines pertaining to ambulatory ECG monitoring in patients with AF. In 2007, the Heart Rhythm Society (HRS), the European Heart Rhythm Association (EHRA) and European Cardiac Arrhythmia Society (ECAS) stated that ‘the more intensively a patient is monitored and the longer the period of monitoring, the greater the likelihood of detecting both symptomatic and asymptomatic AF’ [13]. In 2016, the ESC guidelines state that intensity and duration of monitoring should be influenced by the clinical impact of AF detection [1].

This study is the first to use PPMs as the comparator for evaluation of ECM accuracy. Continuous arrhythmia monitoring by implanted cardiac devices is the accepted ‘gold standard’ for AF diagnosis [14, 15]. Devices vary in their capability to detect and record atrial high rate episodes and are manufacturer specific. All the devices in this study had excellent proven diagnostic capability. All PPMs underwent frequent device downloads, and atrial lead sensing was rechecked to ensure no over- or under-sensing occurred throughout the study period. All of the PPMs provided full data disclosure with electrograms allowing confirmation of the detected arrhythmia on each occasion.

Whilst dual-chamber PPMs are the optimal tool for AF detection and monitoring, they are not primarily implanted as cardiac rhythm monitors [10, 14]. All other studies either compare novel ECMs with each other or against the clinical standard 24-h Holter monitor [16, 17]. The current study is the first long-term beat-to-beat assessment of the efficacy of ECMs in AF detection and is a true test of the accuracy of ECM devices.

The majority of studied patients (18) had PAF, and three had persistent AF. The persistent AF patients were important to include to assess for ECG data inaccuracy due to over or under-sensing, with unequivocal confirmation of rhythm via the DDDRP PPM Holters. This has significant clinical implications regarding anticoagulation.

The indication for prolonged ECG monitoring strategies is the detection of arrhythmias that can cause embolic events. The most important clinical decision in the management of AF is the need for anticoagulation. However, the duration of AF clinically important enough to warrant initiation of anticoagulation remains unclear and changes with the population studied. AHA/ACC/HRS guidelines state that an episode of 30 s or more is clinically significant [2]. However, a 2.5-fold increased risk of stroke has been reported in device patients with AF episodes of > 6 min [14]. The future of cardiac monitors will be influenced by emerging data detailing patient outcome from prospective multicentre studies addressing this clinical question e.g. the ongoing NOAH trial evaluating the clinical implication of atrial high rate episodes for > 6 min [18].

The current study addresses the accuracy of AF detection not the clinical relevance of episode duration, and therefore, we have analysed AF episodes according to both internationally recognized definitions [2, 18], but omitted very short duration AF (< 30 s) episodes, which are likely to be less clinically relevant.

The RT is widely used in UK, Europe, Asia and Africa [11]. This device correlates poorly with DDDRP PPM AF detection, and this should be taken into account when making clinical decisions regarding anticoagulation or to undertake an AF ablation. All the new ECMs are more accurate than RT for both detecting AF and confirming its absence. Given the importance of accurate AF detection, the results of this study support the introduction of these ECMs to routine clinical practice to improve AF diagnostics, to prevent stroke and tachycardia-cardiomyopathy. Potential causes for inaccurate arrhythmia detection by RT include malapplication (frequently required to be undertaken by the patient without supervision); increased body mass index and more active patients are prone to more artefact with this device.

This study confirms that each investigated ECM provided excellent correlation with PPM-derived AF burden and were superior to RT. Likewise, individual episodic data was more accurate for all the study ECMs with excellent correlation for the CAM and NV devices particularly. Performance improved with longer duration AF episodes especially the RT.

Inaccurate diagnoses of very short episodes are unlikely to be clinically relevant apart from highly symptomatic patient-activated episodes or high CHA_2DS_2Vasc score [19]. Further, short duration findings may be dependent on the reading centre directives on reporting.

The ZM combines beat-to-beat analysis with the manufacturer's software (Intelligent Bridging®), to provide improved assessment of AF duration. This study has alleviated theoretical concerns that the algorithm could lead to overestimation of AF duration and excellent correlation with PPM Holters was confirmed.

NV showed superior AF burden detection than RT. This device has the potential for much longer-term monitoring, and a recent study confirms 90-day wear time and thus good potential for cryptogenic stroke detection and management [12].

The CAM was not only superior to RT for AF burden assessment but also excellent at individual AF episode detection. The CAM's placement on top of the atria over the sternum and away from muscle stimulation-generated noise was better tolerated and results in superior AF detection. The CAM device utilizes one chest lead, and the results highlight the importance of anatomical placement of ECMs to provide an optimal ECG axis for accurate rhythm detection.

The ZM had a longer wear time than RT, but it is designed for continuous use for up to 14 days. Previous studies have found an incremental value of arrhythmia detection with cardiac monitoring for longer periods [6] and is likely to be one of the reasons that ZM was found to be superior in AF detection. There were no significant differences in wear time between the other study ECMs and the RT. The RT is removed for a period every day to replace the two electrodes. The NV is also removed daily to recharge the device. The CAM is designed for only 1 week of continuous monitoring. The study participants were therefore fitted with an initial CAM and required to apply a further CAM after the first week of the monitoring period had elapsed. This was undertaken without complication by all study patients.

Each study ECM resulted in less patient time expenditure and less patient costs than the RT. All the newer devices required one journey to and from the hospital. After the monitoring period elapsed, the monitors were removed by the patient and placed in the free postage box provided by the manufacturers or agents, avoiding patient return to hospital. Patients thus save time and avoid travel and parking costs.

The ECM devices were analysed by the manufacturers' or agent except the CAM which was analysed by an independent technician allocated by the UK agents. The RT, however, was analysed by hospital physiologists as per our standard clinical practice. The savings on technician costs and time allow them to provide alternative clinical services.

The CAM was found to be more acceptable to patients than the RT. Previous studies have emphasized the importance of patient satisfaction in the effectiveness of cardiac monitors [20]. Although this study had only 21 participants, they acted as their own control subjects, allowing accurate device comparison of this important parameter.

All the study ECMs were more expensive than the RT largely due to the RT being a reusable device that can be applied to over 400 patients during its expected longevity, whereas the study ECMs are single use only. The cost per accurate diagnosis was not evaluated in this study, as it was not powered to do so. However, given the importance of accurate AF detection to avoid patient morbidity and mortality, the increased costs may be acceptable.

8 Conclusions

All study ECMs were significantly superior in AF burden detection compared with the RT using PPM Holters as the reference standard comparator which has never before been used to assess ECMs in this way. Individual AF episode detection was also superior for ZM and CAM compared to the RT clinical standard. Performance of all ECMs improved with longer duration AF episodes. The ZM had a significantly longer wear time than the RT, whilst the CAM was more acceptable to patients than the RT. All the study ECMs were associated with less patient time expenditure during the monitoring period than the RT, but the RT is significantly cheaper than all studied ECMs, as it is reusable. The relative inaccuracy of RT may have clinical implications.

9 Study limitations

Simultaneous application of all ECMs would improve statistical power and evaluation, but positioning of the devices would cause potential signal interference and the vest would cause artefact on the two patches studied. In addition, patient acceptability could not be assessed. However, each of the 21 patients acted as their own control subject.

As paroxysmal AF can vary in its incidence over time, use of one device for a relatively limited period may have led to differing episode numbers and duration for each device. With limited patient numbers, this could affect arrhythmic incidence per device. However, order of device application was randomized, and therefore, there was no systematic bias.

All the participants in this study had DDDRP PPMs in situ. This is the key strength of the study model but may limit generalizability of our findings, due to other cardiac pathology and did not allow assessment of the ECMs in 'healthy' individuals. However, AF occurred in all patients studied and detection, and episode duration was the aim of the study. DDDRP PPMs are not used in the general population for AF detection and were used only to test the relative accuracy of the RT to three alternative ECMs. The majority of the devices were Medtronic with identical AF detection criteria. Twenty per cent of devices were from other manufacturers, but all have well validated and similar detection criteria and Holter technology which is the gold standard for AF monitoring.

Compliance with ethical standards

Conflict of interest WE has nothing to disclose. NF has nothing to disclose. NS has financial disclosures as specified below:

Unrestricted research grants received from iRhythm San Francisco, CA, USA, NUUBO Smart Solutions Technologies, SL, Madrid and Bardy Diagnostics Inc., Seattle, WA, USA.

Ethical approval This study was performed at Eastbourne Hospital, East Sussex Healthcare NHS Trust, and complies with the declaration of Helsinki. The national research ethics committee approved the study. Written informed consent was obtained from all participants.

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